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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,340	09/29/2000	John R. Subjeck	126.1-US-U3	2180

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EXAMINER
RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/676,340	Applicant(s) SUBJECK ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election Facsimile Cover Sheet* .

DETAILED ACTION

1. Claims 1-45 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-10, 16-18, 22, 23, 33, and 34, insofar as the claims are drawn to a pharmaceutical composition comprising hsp110 and an immunogenic polypeptide associated with cancer and to a method for using said pharmaceutical composition, classified in class 424, subclass 277.1.

Group 2. Claims 1-7, 9, 10, 16-18, 22, 23, 33, and 34, insofar as the claims are drawn to a pharmaceutical composition comprising grp170 and an immunogenic polypeptide associated with cancer and to a method for using said pharmaceutical composition, classified in class 424, subclass 277.1.

Group 3. Claims 1-10, 19-21, 22, 23, and 32, insofar as the claims are drawn to a pharmaceutical composition comprising hsp110 and an immunogenic polypeptide associated with infectious disease and to a method for using said pharmaceutical composition, classified in class 424, subclass 277.1.

Group 4. Claims 1-7, 9, 10, 19-21, 22, 23, and 32, insofar as the claims are drawn to a pharmaceutical composition comprising grp170 and an immunogenic polypeptide associated with infectious disease and to a method for using said pharmaceutical composition, classified in class 424, subclass 277.1.

Group 5. Claims 11-15 and 35, insofar as the claims are drawn to a pharmaceutical composition comprising an antigen presenting cell modified to present hsp110 and an immunogenic polypeptide associated with cancer and a method for using said pharmaceutical composition, classified in class 424, subclass 93.21.

Group 6. Claims 11-15 and 35, insofar as the claims are drawn to a pharmaceutical composition comprising an antigen presenting cell modified to present grp170 and an immunogenic polypeptide associated with cancer and a method for using said pharmaceutical composition, classified in class 424, subclass 93.21.

Group 7. Claims 24-26, insofar as the claims are drawn to a method for producing T cells directed against a tumor cell comprising contacting T cells with an antigen presenting cell modified by contact with hsp110 and an immunogenic polypeptide associated with the tumor cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.

Group 8. Claims 24-26, insofar as the claims are drawn to a method for producing T cells directed against a tumor cell comprising contacting T cells with an antigen presenting cell modified by contact with grp170 and an immunogenic polypeptide associated with the tumor cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.

Group 9. Claims 27, 36, and 37, insofar as the claims are drawn to a method for killing or removing tumor cells comprising contacting a biological sample with a T cell produced by the method of claim 24, which comprises contacting T cells with an antigen presenting cell modified by contact with hsp110, classified in class 435, subclass 373.

Group 10. Claims 27, 36, and 37, insofar as the claims are drawn to a method for killing or removing tumor cells comprising contacting a biological sample with a T cell produced by the method of claim 24, which comprises contacting T cells with an antigen presenting cell modified by contact with grp170, classified in class 435, subclass 373.

Group 11. Claims 28-30, insofar as the claims are drawn to a method for producing T cells directed against a *M. tuberculosis*-infected cell comprising contacting T cells with an antigen presenting cell modified by

contact with hsp110 and an immunogenic polypeptide associated with the *M. tuberculosis*-infected cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.

Group 12. Claims 28-30, insofar as the claims are drawn to a method for producing T cells directed against a *M. tuberculosis*-infected cell comprising contacting T cells with an antigen presenting cell modified by contact with grp170 and an immunogenic polypeptide associated with the *M. tuberculosis*-infected cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.

Group 13. Claim 31, drawn to a method for killing a *M. tuberculosis*-infected cell comprising contacting the cell with a T cell produced by the method of claim 28, which comprises contacting T cells with an antigen presenting cell modified by contact with hsp110, classified in class 435, subclass 373.

Group 14. Claim 31, drawn to a method for killing a *M. tuberculosis*-infected cell comprising contacting the cell with a T cell produced by the method of claim 28, which comprises contacting T cells with an antigen presenting cell modified by contact with grp170, classified in class 435, subclass 373.

Group 15. Claims 38 and 39, insofar as the method for inhibiting tumor growth in a subject comprising incubating T cells with an antigen presenting cell modified to present hsp110 and an immunogenic polypeptide associated with the tumor, classified in class 424, subclass 93.1.

Group 16. Claims 38 and 39, insofar as the method for inhibiting tumor growth in a subject comprising incubating T cells with an antigen presenting cell modified to present grp170 and an immunogenic polypeptide associated with the tumor, classified in class 424, subclass 93.1.

Group 17. Claims 40-42, insofar as the claims are drawn to a method for enhancing an immune response to an antigen in a subject comprising

administering hsp110 to the subject, classified in class 424, subclass 278.1.

Group 17. Claims 40-42, insofar as the claims are drawn to a method for enhancing an immune response to an antigen in a subject comprising administering grp170 to the subject, classified in class 424, subclass 278.1.

Group 18. Claims 43-45, insofar as the claims are drawn to a method for enhancing the immunogenicity of a stress protein complex comprising hsp110, classified in class 424, subclass 278.1.

Group 19. Claims 43-45, insofar as the claims are drawn to a method for enhancing the immunogenicity of a stress protein complex comprising grp170, classified in class 514, subclass 12.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups 1-6, 9, 10, 13, and 14 are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups 1-8, 11, 12, and 15-19 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

Inventions in groups 7, 8, 10, and 11 and groups 9, 10, 13, and 14, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such measuring the cell's activation in response to antigenic stimulation.

The inventions in groups 9, 10, 13, and 14 and groups 1-6 are not at all related because the products of groups 9, 10, 13, and 14 are not specifically used in any of the steps of the claimed methods in groups 1-6.

The inventions in groups 1-6, 9, 10, 13, and 14 and groups 15-19 are not at all related because the products of groups 1-6, 9, 10, 13, and 14 are not specifically used in any of the steps of the claimed methods in groups 15-19.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed inventions and for each generic claim Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7, 8, and 21 are generic.

Claim 7 is drawn to patentably distinct species of the pharmaceutical composition of claim 1 wherein the stress protein complex further comprises (a) hsp70, (b) hsp90, (c) grp78, or (d) grp94. Accordingly, Applicants are required to elect a single disclosed species, i.e., (a), (b), (c), or (d) for prosecution on the merits.

Claim 8 is drawn to patentably distinct species of the pharmaceutical composition of claim 1 wherein the stress protein complex comprises (a) hsp70 or (b) hsp25. Accordingly, Applicants are required to elect a single disclosed species, i.e., (a) or (b) for prosecution on the merits.

Claim 21 is drawn to patentably distinct species of the pharmaceutical composition of claim 20 wherein the antigen is (a) Mtb8.4 or (b) Mtb39. Accordingly, Applicants are required to elect a single disclosed species, i.e., (a) or (b) for prosecution on the merits.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

DONNY WORTMAN
PRIMARY EXAMINER

slr
January 29, 2002

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